

Application Serial No. 10/562,935  
Response to Office Action dated August 17, 2009

PATENT  
Docket: CU-4618

### **REMARKS**

At the issuance of the Office Action, claims 29 and 32-39 are rejected and claims 7-28 and 30 are withdrawn from consideration. The Applicant asserts that the rejections are overcome by amendment or are traversed by the remarks below. No new matter has been added by way of the amendment.

In a telephonic interview on July 31, 2009, the Examiner and counsel for the Applicant discussed the claims and agreed that the amendment filed April 17, 2009 is responsive to the previous Office Action. The Examiner agreed, therefore, to vacate the Notice of Non-responsive Amendment. The Applicant thanks the Examiner for his time.

In addition, counsel for the Applicant left a message for the Examiner asking that the Examiner clarify whether adding the phrase "to a subject in need thereof" to claim 29 would overcome the rejections thereto. The Examiner on February 16, 2010, over the phone, indicated that the phrase would overcome the rejection of claim 29. The Applicant thanks the Examiner for the interview, and in response, has made the amendment.

In the Abstract, please amend the Abstract section to replace the word "comprises" with "including". The Applicant submits that this amendment is fully responsive to the Examiner's objection on page 2 of the Office Action, and therefore, requests that the Examiner withdraw this objection to the Abstract.

In the Claims, claim 38 has been amended to correct dependency. Claim 29 has been clarified to read that the method is a "...treatment for improving the absorption of amino acids for a vertebrate in need thereof...". No new matter has been added by way of these amendments. The amendments to the claims can be viewed in the Amendments section of this paper in the Listing of claims beginning on page 5.

**On page 4 of the Office Action, the Examiner rejected claim 38 under 35**

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**U.S.C. §112, second paragraph, for being indefinite.** In response, the Applicant has amended the claim to reflect accurate dependency from claim 29. The Applicant believes that the amendments to the claims are fully responsive to the rejection and overcomes the rejection. The Applicant respectfully requests that the Examiner withdraw this ground of rejection of the claims.

**Claims 29, 32 and 37-39 are rejected under 35 U.S.C. §102(b) as being anticipated by Reidel et al. (Nephron, Vol. 74, No. 2, pages 261-265; 1996).**

The Applicant respectfully disagrees and asserts that all of the features of the claims are not taught by Reidel et al. In fact, the Examiner has indicated that currently amended claim 29 provides amendments that overcome the rejection thereof.

Please note that the Applicant agrees with the Examiner that Reidel et al. discloses that the administration of alpha-ketoglutarate (AKG) together with calcium carbonate effectively improves amino-acid metabolism in hemodialysis patients.

The invention according to claim 29 involves use of AKG to improve the absorption of amino-acids. The Examiner points out that Riedel et al. in particular discloses that the plasma concentrations of essential amino acids proline, leucine and lysine are increased. The Examiner concludes that since essential amino acids by definition need to be obtained from the diet, the skilled person would conclude that the observed increases are due to improved absorption.

The Applicant has previously argued that hemodialysis patients have no particular problem in their absorption of amino-acids from the gut, and this argument has not been questioned by the Examiner. In fact, hemodialysis patients are without exception on a very strict protein-free diet in order to prevent the accumulation of excess ammonium in the body. In the "Patients and Methods section" on page 262, Riedel et al. reports that the patients followed standard dietary recommendations. Under such conditions of extremely low amino-acid content in the diet, the uptake of amino-acids from the gut may be regarded as complete.

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In these patients, the plasma level of essential amino acids is determined by:

- a. uptake from the diet
- b. level metabolism (level of transformation to other compounds)
- c. transport balance between intracellular stores and the plasma
- d. level of excretion (e.g. to urine)
- e. level of losses through dialysis

For the non-essential amino acids, an additional mechanism, f. the level of biosynthesis is additionally present, but otherwise the controlling mechanisms are in fact the same as for essential amino acids. In other words, the plasma levels of both essential and non-essential amino-acids are controlled by several mechanisms, contrary to the Examiner's assertion that the uptake would necessarily have to be affected if the level of essential amino-acids is increased.

Therefore, the fact that the level of essential amino-acids was increased in Riedel et al. does not suggest, let alone prove that the uptake is increased. It is of interest to note that Riedel et al. themselves draw the conclusion that mechanism b. is altered. Importantly, they do not draw the conclusion that the mechanism a. uptake is increased. Thus, the Applicant respectfully believes that the Examiner's reasoning is in error, and that Riedel et al. does not teach, disclose or suggest that the absorption of amino-acids could be improved by using  $\alpha$ -ketoglutarate.

The Applicant submits, therefore, that all of the elements of the claims are not taught by Riedel et al., and therefore, independent claim 29 and the claims depending therefrom, are novel and not anticipated thereby. The Applicant respectfully requests that the Examiner withdraw this ground of rejection.

**Claims 29 and 32-39 are rejected under 35 U.S.C. §103(a) as being unpatentable over Reidel et al., as applied to claims 29-32 and 37-39, and further in view of Plouvier et al. (U.S. Patent Publ. No. 2004/0127413A1) and Shiflett et al.**

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**(Journal of Nutrition, Vol. 98, p. 420-426; 1969.)**

The Applicant respectfully disagrees and submits that the amendments to claim 29 render the claim non-obvious and allowable.

As discussed above, the Applicant asserts that Reidel et al. does not teach all of the features of the Applicant's invention. Specifically, Reidel et al. does not teach, disclose or suggest a method as in claim 29 of using AKG to improve the absorption of amino-acids. Neither Plouvier et al. nor Schiflett et al. cure the deficit found in Reidel et al. Therefore, the Applicant asserts that claim 29 is non-obvious and respectfully requests that the Examiner withdraw this ground of rejection as to claim 29.

It is axiomatic that if an independent claim is allowable, then any claim depending therefrom is also allowable. Since claims 32-39 depend from claim 29, the Applicant respectfully requests that claims 32-39 also overcome the rejections. The Applicant thus respectfully requests that the Examiner withdraw the rejection of claims 29 and 32-39 under 35 U.S.C. § 103(a).

The Applicant believes that this response is responsive to all points raised in the Office Action dated August 17, 2009. The Applicant respectfully contends that all conditions of patentability are met in the pending claims and requests that the amendments be entered into the record. The Applicant respectfully submits that this Application should be in condition for allowance and respectfully requests favorable consideration.

Respectfully Submitted,



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